

REMARKS

This submission is in response to the Restriction Requirement dated April 9, 2003. Claims 1-18 are pending. Consideration of the above identified application, in view of the following remarks, is respectfully requested.

In the Office Action, the Examiner has required election of one of the following groups of claims:

- I. Claims 1-3, drawn to methods for identifying a gene associated with a disease, classified in class 435, subclass 6.
- II. Claims 4-9, drawn to methods for identifying an individual at risk or suffering from a complex disease, wherein said methods utilizes nucleic acid analysis, classified in class 435, subclass 6.
- III. Claims 7-9, drawn to methods for identifying an individual at risk or suffering from a complex disease, wherein said method utilizes protein analysis, classified in class 435, subclass 7.1.
- IV. Claims 10-11, drawn to methods of treatment which utilize anti-sense technology, classified in class 514, subclass 44.
- V. Claims 10-11, drawn to methods of treatment which utilize antibodies or proteins, classified in class 530, subclass 350+, for example.
- VI. Claims 12-14 and 15-18, drawn to methods for identifying an individual at risk or suffering from a complex disease, wherein said method utilizes antibody analysis, classified in class 530, subclass 387.1.

Claim Group Election

In response, Group I, corresponding to claims 1-3, is hereby elected, with traverse. It is respectfully submitted that, at the very least, groups I and II should be rejoined and prosecuted in the same application, for the reasons outlined below.

Groups I and II Should Be Rejoined

The Examiner alleges that groups I-VI set forth unrelated inventions, because they are either directed to different goals or utilize different method steps and reagents. Office Action, paragraph 2.

Under 35 U.S.C. §121, "two or more independent and distinct inventions... in one application may... be restricted to one of the inventions". Inventions are "independent" if there is no distinct relationship between the two or more subjects disclosed" (MPEP 802.01). The term "distinct" means that "two or more subjects as disclosed are related... but are capable of separate manufacture, use or sale as claimed, AND ARE PATENTABLE (novel and unobvious) OVER EACH OTHER" (MPEP 802.01) (emphasis in original).

However, even with patentably distinct inventions, restriction is not required unless one of the following reasons appear (MPEP 808.02):

1. Separate classification;
2. Separate status in the art; or,
3. Different field of the search.

Moreover, according to Patent Office examining procedures, "[i]f the search and examination of an entire application can be made without serious burden, the Examiner must examine it on the merits, even though it includes claims to distinct or independent inventions" (MPEP 803) (emphasis added).

Applicants respectfully submit that the groups designated by the Examiner fail to define inventions that warrant separate examination and search. The claims of group I are directed to a method of identifying a gene involved in a complex disease by identifying a region of the genome neighboring a disease-associated marker, comparing a sequence of a regulatory region of a consensus L1 sequence to an intronic region of a gene involved in a complex disease, and identifying genes containing a full-length L1 element in their intronic region or containing a full-length L1 element with high sequence fidelity to the L1 consensus sequence in their 5' or 3' regulatory region.

The claims of group II are directed to a method of identifying an individual at risk for or suffering from a complex disease comprising the steps of providing a sample from said individual, identifying intronic regions of genes involved in a complex disease and containing full-length L1 elements or in 5' or 3' regulatory regions of such genes containing a full-length high fidelity consensus L1 sequence of the individual's DNA from said sample and comparing said intronic regions of genes or said 5' or 3' regulatory regions with a control sample of DNA

taken from an individual not susceptible to or at risk for or currently suffering from a complex disease

Groups I and II designated by the Examiner thus fail to define methods that warrant separate examination and search. Claims 1-9 represent a web of knowledge and continuity of effort that merits examination in a single application. In particular, the basis for traversal is that the subject matter of Group II cannot be examined without examination of the subject matter of Group I, for the reasons outlined below:

- The subject matter of claim groups I and II has been classified into the same class (435) and subclass (6).
- Both claim group utilize nucleic acid analysis based on L1 elements and genes involved in complex diseases. Accordingly, a thorough search of the subject matter of Claim group II would necessarily include a search of the subject matter of Claim group I as they all involve the same features of the host cell library.

Thus, the search and examination of each group is necessarily co-extensive, and in any event would involve such interrelated art that the search and examination of the entire application can be made without undue burden on the Examiner. Accordingly, Applicants respectfully request that the Examiner withdraw the Requirement for Restriction, at least as applied to Claim Groups I and II, and that claims 1-9 be examined in a single application.

Species Election

The Office Action also requires the election of a single complex disease species. In response, systemic lupus erythematosus is elected as the complex disease species. It is noted that upon allowance of a generic claim, Applicants will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim.

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Early and favorable consideration of this response and the claims is earnestly solicited. If there are any other issues remaining which the Examiner believes could be resolved through either a Supplemental Response or an Examiner's Amendment, the Examiner is respectfully requested to contact the undersigned at the telephone number indicated below.

Respectfully submitted,



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Limited Recognition Under 37 C.F.R.
10.9(b) (see attached)
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